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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/711,784	11/13/2000	Chris De Bruijn		8210

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EXAMINER

MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 07/14/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/711,784

Applicant(s)

DE BRUIJN ET AL.

Examiner

Leigh McKane

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-51, 53-57 and 60-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53-57 and 60-64 is/are allowed.
- 6) ☒ Claim(s) 46-51 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Continued Prosecution Application

1. The request filed on 09 June 2003 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/711,784 is acceptable and a CPA has been established. An action on the CPA follows.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 46 and 64 are rejected under 35 U.S.C. 102(b) as being anticipated by Mohan et al (Abstract of “Anti-cataract effect of topical quercetin and myricetin in galactosemic rats”).

Mohan et al teaches a hydrogen peroxide-free ophthalmic solution comprising quercetin in an amount of 0.5% (5000 ppm). Although Mohan et al does not disclose that the solution is preserved by the quercetin, the quercetin is added in a microbicidally effective amount and no other preservative is used within the solution.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1744

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 47-49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mohan et al in view of Hofmann et al.

Although Mohan et al teaches an ophthalmic composition, adjuvants suitable for use within the composition are not disclosed. Hofmann et al discloses an ophthalmic composition that contains a sequestering agent EDTA for eliminating heavy metal binding and improving lens pliability, a viscosity altering agent PVA for increasing solution adherence to the corneal surface, a surfactant, known for improving surface contact and dispersion, and tonicity adjusters. As the composition of Mohan et al, like Hofmann et al, is directed to preventing and treating eye disorders, it would have been obvious to include the adjuncts of Hofmann et al therein.

7. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mohan et al and Hofmann et al, as set forth above and further in view of Chiou (U.S. Patent no. 5,182,258).

The combination *supra* teaches an ophthalmic composition employing surfactants but does not disclose using saponin as the surfactant. Chiou discloses an ophthalmic composition which may contain "surfactants such as saponins" (col.8, lines 64-65). As saponin is a surfactant safe for use in the eye, it would have been obvious to one of ordinary skill in the art to use a saponin as the surfactant of Yamakoshi et al with Hofmann et al.

Art Unit: 1744

Claim Objections

8. Claim 46 is objected to because of the following informalities: In line 2, "153-,000" should be corrected to read -10,000--. Appropriate correction is required.

Allowable Subject Matter

9. Claims 53-57 and 60-63 are allowed.

10. The following is an examiner's statement of reasons for allowance: With respect to claim 61, the closest prior art Yamakoshi et al, fails to teach an ophthalmic composition containing a microbial preservative consisting essentially of 10-10,000 ppm of proanthocyanidins. As to claims 62 and 63, the prior art fails to teach or suggest an ophthalmic solution containing oleuropein.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Squires (WO98/11778) teaches a composition that may be used to treat HSV infection in the eyes wherein the composition contains Echinacea extract in a concentration of 2-90%, a much higher concentration than that claimed by the present invention. There is no motivation to decrease the concentration below 2% since doing so may impair the antimicrobial


Art Unit: 1744

activity of the composition. In contrast, the present invention employs a lower concentration of Echinacea extract for preservation of the composition itself.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 703-305-3387. The examiner can normally be reached on Monday-Wednesday (7:15 am-4:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Leigh McKane
Primary Examiner
Art Unit 1744

elm
July 9, 2003